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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,041	05/01/2001	Martin S. Linsell	P-086-R	5226

27038 7590 10/02/2003

THERAVANCE, INC.
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EXAMINER	
DESAI, ANAND U	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 10/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/847,041	LINSELL ET AL.	
	Examin r	Art Unit	
	Anand U Desai	1653	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1-4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

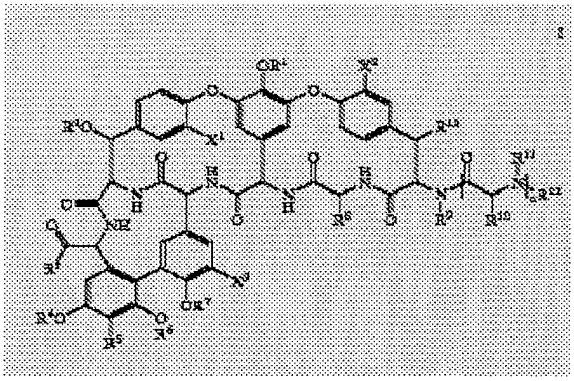
Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

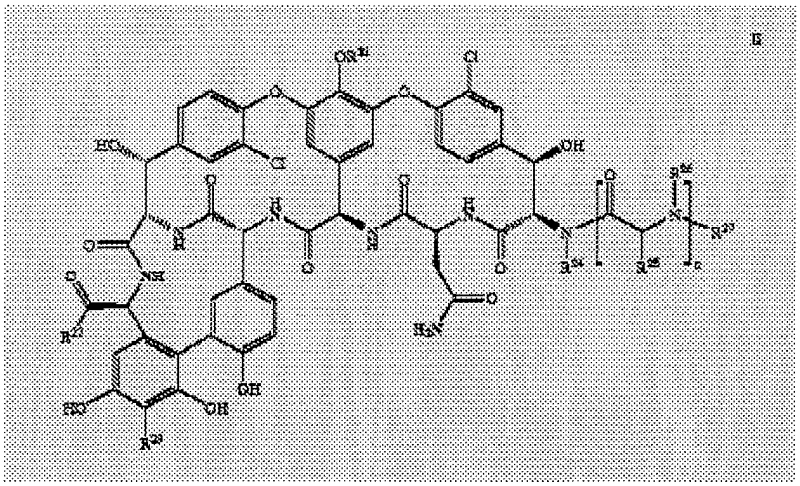
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 12, 31, and 32 of U.S. Patent No. 6,444,786. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds claimed in the instant application are encompassed by the claims in U.S. Patent 6,444,786. The glycopeptides in patent application 6,444,786 are composed of a compound of:



Each of the substituents are enumerated in claim 1 (claim 1, columns 79-81; **Claims 1-4, 8-10**). The compound of claim 1, wherein R^1 is a saccharide group substituted with $-R^a$-Y-R^b-$(Z)_x$ (claim 2, column 81; **Claim 5**). The compound where R1 is a saccharide group wherein R^{15} is $-R^a$-Y-R^b-$(Z)_x$, and R^{16} is hydrogen or methyl (claim 3, columns 81-82; **Claim 6**). The compound where R^{15} is $-R^a$-Y-R^b-$(Z)_x$, selected from the group in claim 4 (claim 4, column 82; **Claim 7**). The compound in claim 1, where R^3 is $-NR^cR^e$, and R^e is a saccharide group. The R^c can also be a substituted alkyl (claim 1, columns 79-81; **Claims 8-11**). The glycopeptides of U.S. Patent 6,444,786 claims a compound of formula II shown as:



Each of the substituents are enumerated in claim 12 (claim 12, columns 82-85). When the R^{21} member is a substituted saccharide group in the instant application, where the R^{21} contains a R^{15} and R^{16} substituent that can be defined such that R^{15} is $-R^a$-Y-R^b-$(Z)_x$, R^{16} is hydrogen, R^{23} is hydrogen, R^{22} is $-NR^cR^c$, where R^c can be a substituted alkyl, alkyl, or hydrogen the instant U.S. Patent teaches the compound of claim 12 (claim 12, column 82-85; **Claim 12**). Judice et al. also teaches a pharmaceutical composition

comprising a pharmaceutically-acceptable carrier and a compound of any claims 2, 20, 21-30 of U.S. Patent 6,444,786 (claim 31, column 86; **Claims 13-14**). Judice et al. also teaches a method of inhibiting the growth of bacteria in a mammal infected with bacteria, the method comprising administering to the mammal a composition according to claim 31 for a time and under conditions effective to inhibit growth of bacteria (claim 32, column 86; **Claims 15-18**).

3. Claims 1-4, 6, 8, 9, 12-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 6, 8, 9, 11-13, 17-22 of U.S. Patent No. 6,620,781. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant U.S. Patent claims a glycopeptide comprising a carboxy terminus, wherein the glycopeptide is substituted at the carboxy terminus with a substituent comprising a dicarboxylic acid (claims 1). The substituents are further defined in claims 3, 6, 8, and 9 which encompass the claimed compound in the instant U.S. Patent Application 09/847041 (claims 3, 6, 8, 9, 11-13; **Claims 1-4, 6, 8, 9, 12**). The instant U.S. Patent also claims a pharmaceutical composition comprising a pharmaceutically acceptable carrier and a therapeutically effective amount of a glycopeptide. The pharmaceutical composition comprises a cyclodextrin (claim 17, and 18, columns 49-50; **Claims 13, and 14**). The Patent also claims a method of treating a mammal having a bacterial disease, the method comprising administering to the mammal a therapeutically effective amount of a glycopeptide or a pharmaceutical composition (claims 19, 20, 21, and 22; **Claims 15-18**).

Claim Rejections - 35 USC § 102

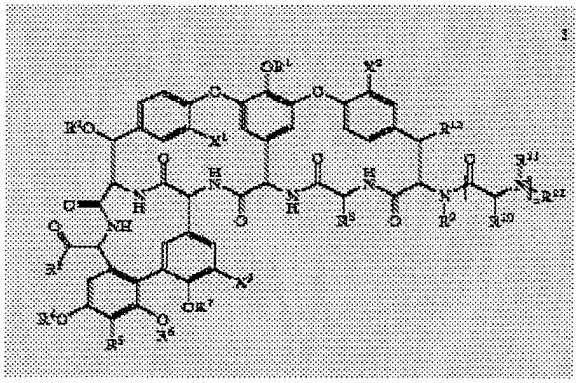
4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

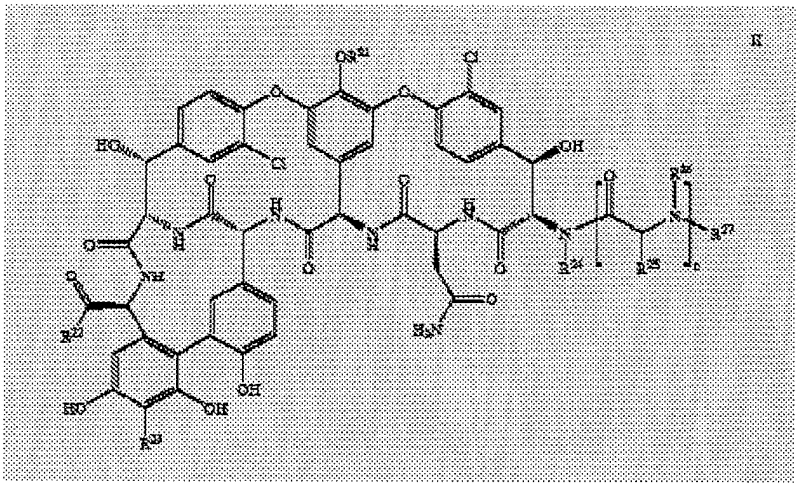
Claims 1-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Judice et al. U.S. Patent 6,444,786 (Effective filing date= Dec 23, 1998).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The compounds claimed in the instant application are encompassed by the claims in U.S. Patent 6,444,786. The glycopeptides in patent application 6,444,786 are composed of a compound of:



Each of the substituents are enumerated in claim 1 (claim 1, columns 79-81; **Claims 1-4, 8-10**). The compound of claim 1, wherein R^1 is a saccharide group substituted with $-R^a$-Y-R^b-$(Z)_x$ (claim 2, column 81; **Claim 5**). The compound where R1 is a saccharide group wherein R^{15} is $-R^a$-Y-R^b-$(Z)_x$, and R^{16} is hydrogen or methyl (claim 3, columns 81-82; **Claim 6**). The compound where R^{15} is $-R^a$-Y-R^b-$(Z)_x$, selected from the group in claim 4 (claim 4, column 82; **Claim 7**). The compound in claim 1, where R^3 is $-NR^cR^e$, and R^e is a saccharide group. The R^c can also be a substituted alkyl (claim 1, columns 79-81; **Claims 8-11**). The glycopeptides of U.S. Patent 6,444,786 claims a compound of formula II shown as:

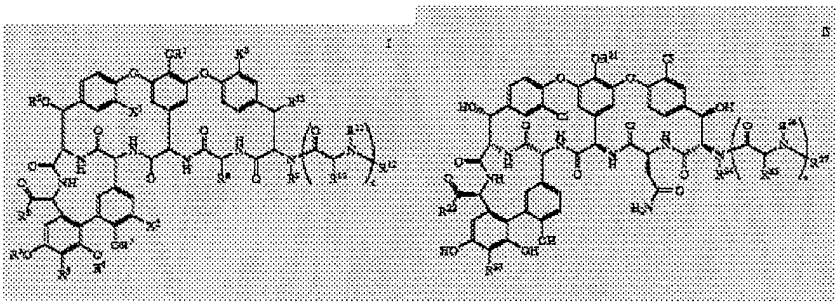


Each of the substituents are enumerated in claim 12 (claim 12, columns 82-85). When the R^{21} member is a substituted saccharide group in the instant application, where the R^{21} contains a R^{15} and R^{16} substituent that can be defined such that R^{15} is $-R^a\text{-}Y\text{-}R^b\text{-}(Z)_x$, R^{16} is hydrogen, R^{23} is hydrogen, R^{22} is $-NR^cR^c$, where R^c can be a substituted alkyl, alkyl, or hydrogen the instant U.S. Patent teaches the compound of claim 12 (claim 12, column 82-85; **Claim 12**). Judice et al. also teaches a pharmaceutical composition comprising a pharmaceutically-acceptable carrier and a compound of any claims 2, 20, 21-30 of U.S. Patent 6,444,786 (claim 31, column 86; **Claims 13-14**). Judice et al. also teaches a method of inhibiting the growth of bacteria in a mammal infected with bacteria, the method comprising administering to the mammal a composition according to claim 31 for a time and under conditions effective to inhibit growth of bacteria (claim 32, column 86; **Claims 15-18**).

5. Claims 1-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Judice et al. U.S. Patent 6,392,012 (Effective filing date= December 23, 1998).

The applied reference has a common Assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 1-12 are directed to substituted glycopeptide compounds which are taught by Judice et al. (columns 1-41, and claims 1-33). The compounds are of formula I, and II shown below:



Where the substituents are enumerated in the claims (claims 1-33, columns 85-92; **Claims 1-12**). Judice et al. also teaches a pharmaceutical composition comprising a glycopeptide compound, and a pharmaceutically acceptable carrier (claim 34, column 92; **Claims 13-14**). Judice et al. also teaches a method of inhibiting growth of bacteria in a mammal infected with bacteria, the method comprising administering to the mammal a composition according to claim 34 for a time and under conditions effective to inhibit growth of bacteria (claim 35, column 92; **Claims 15-18**).

September 25, 2003

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER